

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

IN RE: TESTOSTERONE	)	
REPLACEMENT THERAPY	)	Case No. 14 C 1748
PRODUCTS LIABILITY LITIGATION	)	
	)	MDL No. 2545
This Document Relates to:	)	
Case No. 14-cv-1483 (Cataudella);	)	Judge Matthew F. Kennelly
Case No. 14-cv-1298 (Lau); and	)	
Case No. 14-cv-2394 (Parker)	)	

**REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS  
ENDO PHARMACEUTICALS INC.'S, ELI LILLY AND COMPANY AND LILLY USA,  
LLC'S, AND AUXILIUM PHARMACEUTICALS, INC.'S MOTION TO JOIN AND  
SUPPLEMENT DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINTS**

## TABLE OF CONTENTS

	<u>Page</u>
PRELIMINARY STATEMENT .....	1
ARGUMENT .....	2
I. The Court Should Dismiss Cataudella’s, Lau’s, and Parker’s Fraud and Negligent Misrepresentation Claims Against Endo, Lilly, and Auxilium Under Rule 9(b). ....	2
II. The Court Should Dismiss All of Cataudella’s, Lau’s, and Parker’s Claims Against Endo, Lilly, and Auxilium Under Rule 8(a). ....	5
III. The Law Applicable To Each Plaintiff Bars Some of Cataudella’s, Lau’s, and Parker’s Claims. ....	6
A. The Court Should Rule on Cataudella’s, Lau’s, and Parker’s State Law Claims. ....	6
B. The Court Should Dismiss Certain State Law Claims Raised by Cataudella, Lau, and Parker. ....	7
CONCLUSION.....	7

## TABLE OF AUTHORITIES

	<u>Page(s)</u>
<b>CASES</b>	
<i>Beavers-Gabriel v. Medtronic, Inc.</i> , 2014 WL 1396582 (D. Haw. Apr. 10, 2014) .....	3
<i>Borsellino v. Goldman Sachs Grp., Inc.</i> , 477 F.3d 502 (7th Cir. 2007) .....	2
<i>Buckman Co. v. Plaintiffs' Legal Comm.</i> , 531 U.S. 341 (2001) .....	2
<i>DiLeo v. Ernst &amp; Young</i> , 901 F.2d 624 (7th Cir. 1990) .....	2
<i>Frazier v. Mylan Inc.</i> , 911 F. Supp. 2d 1285 (N.D. Ga. 2012) .....	5
<i>In re Ameriquest Mortg. Co. Mortg. Lending Practices Litig.</i> , 2008 WL 630883 (N.D. Ill. Mar. 5, 2008) .....	6
<i>In re Armored Car Antitrust Litig.</i> , 462 F. Supp. 394 (J.P.M.L. 1978) .....	6
<i>In re Rezulin Prods. Liab. Litig.</i> , 133 F. Supp. 2d 272 (S.D.N.Y. 2001) .....	6
<i>In re Shop-Vac Mkt. and Sales Practices Litig.</i> , 964 F. Supp. 2d 335 (M.D. Pa. 2013) .....	6
<i>Larkins v. Glaxo Wellcome, Inc.</i> , 1999 WL 360204 (E.D.N.Y. May 20, 1999) .....	5
<i>Martin v. Medtronic, Inc.</i> , 2014 WL 3635292 (D. Ariz. July 23, 2014) .....	3
<i>Morse v. Abbott Labs.</i> , 765 F. Supp. 1108 (N.D. Ill. 1991) .....	3
<i>Rosenstern v. Allergan, Inc.</i> , 987 F. Supp. 2d 795 (N.D. Ill. 2013) .....	3, 4
<i>Vicom, Inc. v. Harbridge Merch. Servs. Inc.</i> , 20 F.3d 771 (7th Cir. 1994) .....	2

**RULES**

Federal Rule of Civil Procedure 12(b)(6) .....	1
Federal Rule of Civil Procedure 8(a) .....	1, 5, 6, 7
Federal Rule of Civil Procedure 9(b).....	<i>passim</i>

## **PRELIMINARY STATEMENT**

Defendants Endo Pharmaceuticals Inc. (“Endo”), Eli Lilly and Company and Lilly USA, LLC (collectively, “Lilly”), and Auxilium Pharmaceuticals, Inc. (“Auxilium”) join Defendants’ Reply in Support of Their Motion to Dismiss Complaints (“Defendants’ Reply”), and adopt and incorporate by reference the factual and legal arguments set forth therein. Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendants Endo, Lilly, and Auxilium also submit this Joinder and Supplement to assert additional legal and factual bases to dismiss the claims raised in the respective First Amended Complaints (“FACs”) against Endo (Cataudella), Lilly (in Lau), and Auxilium (in Parker).<sup>1</sup>

After Defendants Endo, Lilly, and Auxilium filed their Motion to Join and Supplement Defendants’ Motion to Dismiss, this Court granted Plaintiffs’ oral motion to file amended complaints simultaneously with their opposition briefs.<sup>2</sup> *See* TRT Hearing Tr., July 10, 2014, at 55:10-57:4. On August 15, 2014, Plaintiffs Cataudella (Dkt. # 292-1), Lau (Dkt. # 320-2), and Parker (Dkt. # 273-2) filed FACs.

Even with the benefit of a second bite at the apple, Cataudella, Lau, and Parker fail to plead sufficient specific facts related to Endo, Lilly, and Auxilium, or related to Plaintiffs’ use of these Defendants’ respective Testosterone Replacement Therapy (“TRT”) prescription medications. Therefore, this Court should dismiss the claims in Cataudella (against Endo), in Lau (against Lilly), and in Parker (against Auxilium) under Rules 8(a) and 9(b).

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<sup>1</sup> This Joinder and Supplement does not repeat the factual and legal arguments related to Rules 8(a) and 9(b), which Defendants raise in Defendants’ Reply, and incorporate here by reference. Moreover, in compliance with the Court’s oral ruling, this Joinder and Supplement does not address Cataudella’s, Lau’s, or Parker’s design defect claims. *See* TRT Hearing Tr., August 22, 2014, at 5:4-7:3.

<sup>2</sup> Defendants refer herein to Plaintiffs’ Memorandum of Law in Opposition to Defendants’ AbbVie, Inc. and Abbot Laboratories, Inc. Motion to Dismiss as the “Lead Opp.” and to Plaintiffs’ Memorandum of Law in Opposition to Motion of Defendants Endo Pharmaceuticals Inc., Eli Lilly and Company and Lilly USA, LLC, and Auxilium Pharmaceuticals, Inc. to Join and Supplement Defendants’ Motion to Dismiss Complaints as the “Supp. Opp.”

## ARGUMENT

### **I. The Court Should Dismiss Cataudella's, Lau's, and Parker's Fraud and Negligent Misrepresentation Claims Against Endo, Lilly, and Auxilium Under Rule 9(b).**

In their FACs, Cataudella, Lau, and Parker each fail to identify any specific false statement by Endo, Lilly, or Auxilium that they or their respective prescribing physicians saw or relied upon.<sup>3</sup> Moreover, the only alleged “omissions” that Plaintiffs identify in support of their fraud based claims are the *exact same* “omissions” that Plaintiffs identify in support of their failure to warn claims. Therefore, pursuant to Rule 9(b), the Court should dismiss Cataudella's, Lau's, and Parker's fraud and negligent misrepresentation<sup>4</sup> claims with prejudice.

Cataudella, Lau, and Parker concede that Rule 9(b) requires a plaintiff to plead with heightened particularity “the who, what, when, where, and how” related to the alleged fraud. Suppl. Opp. at p. 9 (citing Lead Opp.), Lead Opp. at p. 32 (citing *DiLeo v. Ernst & Young*, 901 F.2d 624 (7th Cir. 1990) (affirming dismissal of fraud claims for failure to plead with particularity)). Rule 9(b) requires this heightened particularity for claims sounding in fraud to: “(1) protect[] a defendant's reputation from harm; (2) minimiz[e] ‘strike suits’ and ‘fishing expeditions’; and (3) provid[e] notice of the claim to the adverse party.” *Vicom, Inc. v. Harbridge Merch. Servs. Inc.*, 20 F.3d 771, 777 (7th Cir. 1994) (citations omitted).

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<sup>3</sup> As discussed in Defendants' Reply (at pp. 2-3, 12-15, 23), under the learned intermediary doctrine Defendants only had a duty to warn Plaintiffs' doctors, not Plaintiffs. However, it is worth noting that each of these Plaintiffs also fail to plead with specificity that he relied on any allegedly false statement made by Endo, Lilly, or Auxilium. Moreover, to the extent Plaintiffs' argument is that Defendants' promotion for “Low-T” under the FDA-approved indication amounts to Defendants committing fraud on the FDA, such claims are impliedly preempted by the Federal Food, Drug, and Cosmetic Act. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

<sup>4</sup> In the Supplemental Opposition, without any objection, Cataudella, Lau, and Parker address their negligent misrepresentation claims under Rule 9(b) and thus concede that Rule 9(b)'s heightened pleading standard applies to their negligent misrepresentation claims in addition to their fraud claims. See Suppl. Opp. at p. 9; *Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007) (explaining that plaintiff's misrepresentation claim must conform to Rule 9(b) because it was “premised upon a course of fraudulent conduct”).

In the Supplemental Opposition, Cataudella, Lau, and Parker do not even attempt to show the Court (because they cannot) that they plead their fraud based claims with Rule 9(b)'s required heightened particularity. Instead, they simply assert that they satisfied Rule 9(b) because: (1) "each of the Supplemental Defendants," through their respective "advertising and marketing campaigns" "misrepresented that 'hypogonadism' and 'low testosterone' were one and the same, and suggested that its product was approved to treat 'low testosterone,'" and (2) "each of the Supplemental Defendants omitted, and failed to warn about, the dangers of TRT." Supp. Opp. at p. 9.

First, Cataudella's, Lau's, and Parker's references to Endo's, Lilly's, and Auxilium's supposed general "advertising and marketing campaigns" fail to satisfy Rule 9(b)'s heightened pleading standard because each Plaintiff fails to allege any facts that connect any specific advertisement or marketing piece by Endo, Lilly, or Auxilium, respectively, to his physician, to his physician's decision to prescribe Fortesta (to Cataudella), Axiron (to Lau), or Testim (to Parker), or to himself. *See, e.g., Rosenstern v. Allergan, Inc.*, 987 F. Supp. 2d 795, 806 (N.D. Ill. 2013) (dismissing plaintiff's negligent misrepresentation claim because "[p]laintiff's general [marketing and promotional] allegations [were] insufficient to meet the heightened standard of Rule 9(b)"); *Martin v. Medtronic, Inc.*, 2014 WL 3635292, at \*10 (D. Ariz. July 23, 2014) (citing *Beavers-Gabriel v. Medtronic, Inc.*, 2014 WL 1396582, at \*12 (D. Haw. Apr. 10, 2014)) (dismissing plaintiff's fraud based claims because the complaint failed to allege a "connection between Defendants' alleged misdeeds and Plaintiff and Plaintiff's physicians—i.e., that Plaintiff and Plaintiff's physicians relied on these misrepresentations"); *Morse v. Abbott Labs.*, 765 F. Supp. 1108, 1112 (N.D. Ill. 1991) (dismissing plaintiff's fraud and negligent misrepresentation claims because plaintiff improperly argued a "fraud on the market" theory instead of alleging actual reliance with particularity). In *Rosenstern*, for example, the court explained that the plaintiff failed to allege with particularity "what promotional materials contained false statements, the specific content of those false statements, what individuals made

those statements to Rosenstern or her doctors, and when and where those statements occurred.” 987 F. Supp. 2d at 806.

Cataudella’s, Lau’s, and Parker’s FACs suffer these same deficiencies because they fail to plead, among other things: (i) what false statement(s) was made to Cataudella’s, Lau’s, or Parker’s prescribing physician (or Plaintiff); (ii) why any particular statement is false; (iii) when the false statement was made to the prescribing physician; (iv) that Cataudella’s, Lau’s, or Parker’s prescribing physician relied on any allegedly false statement in deciding to prescribe TRT to Cataudella, Lau, and Parker; and (v) the specific advertisement or marketing material containing the allegedly false statement that the prescribing physician saw and relied upon. For example, one of the alleged “advertising and marketing campaigns” that Cataudella points to in the Supplemental Opposition is “a press release from January 5, 2011” in which “Endo announced that the FDA had ‘approved FORTESTA Gel for the treatment of low testosterone, or ‘Low T,’ also known as hypogonadism.’” See Supp. Opp. at pp. 2, 9, citing Cataudella’s FAC ¶ 42. Nowhere in Cataudella’s FAC, however, does he allege that Cataudella’s prescribing physician (or Cataudella) ever saw the press release, that *this* statement in *this* press release impacted Cataudella’s prescribing physician’s decision to prescribe TRT to Cataudella, or does Cataudella explain how the statement is false. Moreover, it is unlikely that in March 2013, when deciding to prescribe Fortesta to Cataudella, Cataudella’s prescribing physician relied on a particular statement from a press release Endo issued two years earlier – in January 2011.

The same is true for Lau’s and Parker’s FACs. Lau and Parker may describe Lilly’s and Auxilium’s alleged general “advertising and marketing campaigns,” but they fail to allege any particular facts related to a false statement that Lau’s or Parker’s prescribing physician saw and relied upon when they made their respective decisions to prescribe TRT to Lau and Parker.<sup>5</sup> Lau and Parker also fail to explain why the alleged statements are false.

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<sup>5</sup> Parker’s FAC serves as an excellent example of this failing. Specifically, Parker alleges



Second, Cataudella's, Lau's, and Parker's assertion that they satisfied Rule 9(b) because the "Supplemental Defendants omitted, and *failed to warn* about, the dangers of TRT" is meritless because a Plaintiff cannot satisfy Rule 9(b) by simply restating his failure to warn claim under the heading "fraud." *See, e.g., Frazier v. Mylan Inc.*, 911 F. Supp. 2d 1285, 1298, 1303 (N.D. Ga. 2012) (dismissing with prejudice plaintiff's fraud claim because it was "a restatement of her failure to warn claim"); *Larkins v. Glaxo Wellcome, Inc.*, 1999 WL 360204, at \*10 (E.D.N.Y. May 20, 1999) (dismissing plaintiff's fraud claim because it "merely restates the failure to warn allegation"). Cataudella, Lau, and Parker candidly admit in their Supplemental Opposition that their fraud based claims are merely restatements of their failure to warn claims. For example, to support Cataudella's fraud based claims, Plaintiffs cite to paragraphs 150-152 in Cataudella's FAC – paragraphs contained in Cataudella's "Strict Products Liability – Failure to Warn" count. *See* Supp. Opp. at p. 9, citing Cataudella's FAC ¶¶ 150-152. Similarly, Lau and Parker point to the exact same facts to support both their fraud based claims and their failure to warn claims. *See* Supp. Opp. at p. 9, citing Lau's FAC ¶¶ 100-114 and Parker's FAC ¶¶ 129-142. Cataudella's, Lau's, and Parker's FACs fall woefully short of Rule 9(b)'s heightened pleading standard and, therefore, this Court should dismiss these claims with prejudice.

## **II. The Court Should Dismiss All of Cataudella's, Lau's, and Parker's Claims Against Endo, Lilly, and Auxilium Under Rule 8(a).**

In their Supplemental Opposition, Cataudella, Lau, and Parker do not raise any new arguments related to whether their FACs comply with Rule 8(a) that Plaintiffs do not also raise in their Lead Opposition. Thus, Endo, Lilly, and Auxilium direct the Court to pages 1-20 of Defendants' Reply (as well as Endo's, Lilly's, and Auxilium's Supplemental Memo and

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that Auxilium implemented a "Low T Facts" marketing campaign, made available an "Interactive ADAM Questionnaire," and used a "Level Up Plan." Parker's FAC ¶¶ 51-69. Parker also alleges that AbbVie engaged in a large-scale marketing campaign for AndroGel. *Id.* ¶¶ 79-81. Yet, nowhere does Parker allege that either he or his prescribing physician saw or relied upon any of these materials – let alone any specific statement or omission by Auxilium. Instead, Parker summarily states that he used "AndroGel and Testim for symptoms he attributed to low testosterone as a result of *Defendants'* advertisements." *Id.* ¶ 147 (emphasis added).

Defendants' Memo), which sets forth the reasons the Court should dismiss, pursuant to Rule 8(a), all of Cataudella's claims against Endo, Lau's claims against Lilly, and Parker's claims against Auxilium.

**III. The Law Applicable to Each Plaintiff Bars Some of Cataudella's, Lau's, and Parker's Claims.**

**A. The Court Should Rule on Cataudella's, Lau's, and Parker's State Law Claims.**

Cataudella, Lau, and Parker are incorrect that it is "inappropriate" for this Court to address their individual state law claims. *See* Defendants' Reply at pages 4, 23-25. Contrary to Plaintiffs' assertion, the Judicial Panel on Multidistrict Litigation has explained that the "very nature" of MDL proceedings is for the transferee judge "to apply the law of more than one state." *See In re Armored Car Antitrust Litig.*, 462 F. Supp. 394, 396 (J.P.M.L. 1978). Courts around the country have heeded the JPML's advice and applied the law of multiple states. *See, e.g., In re Shop-Vac Mkt. and Sales Practices Litig.*, 964 F. Supp. 2d 335, 366-67 (M.D. Pa. 2013) (dismissing state law fraud claims brought under the laws of forty-nine states because plaintiffs failed to satisfy Rule 9(b)); *In re Ameriquest Mortg. Co. Mortg. Lending Practices Litig.*, 2008 WL 630883, at \*6 (N.D. Ill. Mar. 5, 2008) (reviewing negligent misrepresentation and negligence laws from three states); *In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272 (S.D.N.Y. 2001) (analyzing state law claims from five different states).

Moreover, in their Supplemental Reply, Cataudella, Lau, and Parker created a straw man in an effort to avoid having this Court dismiss certain state law claims; *i.e.*, they suggest that this court is faced with examining "each of the hundreds or thousands of pleadings in this MDL." *See* Supp. Opp. at p. 10. As the Court knows, this simply is not the case. To help steer this litigation in an efficient manner, the Court set up a procedure whereby Defendants filed a Motion to Dismiss that addressed 39 cases (with Plaintiffs from 23 states). A few days after

the JPML officially created this MDL, this Court explained “[p]resumably there’s going to be a lot of other states with a lot of other laws that end up being part of the MDL, but my hunch is that whatever I say about these states is at least going to give some people some guidance on the rest of it.” TRT Hearing Tr., June 9, 2014, at 97:9-14. Thus, as this Court intended all along, the Court should rule on the state law claims raised in Cataudella’s, Lau’s, and Parker’s FACs because it is an efficient way for the Court to address key issues in these cases early in the litigation, and it also will provide guidance to other plaintiffs.

**B. The Court Should Dismiss Certain State Law Claims Raised by Cataudella, Lau, and Parker.**

In their Supplemental Opposition, Cataudella, Lau, and Parker do not raise any new arguments related to their breach of implied warranty, breach of express warranty, and negligent misrepresentation claims that Plaintiffs do not also raise in their Lead Opposition. Thus, Endo, Lilly, and Auxilium direct the Court to pages 12-20, 25-28, and 32 of Defendants’ Reply (as well as Endo’s, Lilly’s, and Auxilium’s Supplemental Memo and Defendants’ Memo), which sets forth the reasons the Court should dismiss: (a) the breach of implied and express warranty claims against Endo, Lilly and Auxilium; and (b) the negligent misrepresentation claim against Auxilium.

**CONCLUSION**

For the reasons set forth above, pursuant to Rules 8(a) and 9(b), the Court should dismiss with prejudice Cataudella’s claims against Endo, Lau’s claims against Lilly, and Parker’s claims against Auxilium. The Court should also dismiss with prejudice Cataudella’s express and implied warranty claims pursuant to Arizona law, Lau’s express and implied warranty claims pursuant to Florida law, and Parker’s negligent misrepresentation claim pursuant to Nevada law.

Dated: September 26, 2014

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Andrew K. Solow, an attorney, hereby certify that on September 26, 2014, I caused a copy of the foregoing document to be filed via the Court's CM/ECF system, which will automatically serve and send e-mail notification of such filing to all registered attorneys of record.

/s/ Andrew K. Solow